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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,967	02/23/2004	James Oliver Dolly	20020065.ORI	6222

23595 7590 10/11/2006
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EXAMINER

ARCHIE, NINA

ART UNIT PAPER NUMBER

1645

DATE MAILED: 10/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding:

Office Action Summary

Application No.

10/049,967

Applicant(s)

DOLLY ET AL.

Examiner

Nina A. Archie

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 48-103 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 48-103 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 48, 50-77, 79-85, drawn to a method of treatment comprising the step of supplying a SNARE to a cell.

Group II claim(s) 49, 51-76, 78-85, drawn to a method of making a medicant.

Group III, claim(s) 86-93, 102, drawn to product comprising a SNARE and a kit.

Group IV, claim(s) 94-103, drawn to nucleic acid encoding a SNARE, recombinant polynucleotide encoding a SNARE, gene therapy delivery system, and a kit.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

1. The technical feature of Group 1 is a method of treating a patient at risk, by administering a SNARE to a cell. The technical feature is anticipated by Foster et al. *American Journal of Physiology* 1999;276:C1108–C1114 (pg. C1108 column 1 paragraph 1, pg. C1109 column 1-2, pg. C1110 Figure 1, C1112 column 2, C1113 column 1) that teaches administration of a SNARE to a patient. Several other references as outlined below also anticipate the technical feature. Chen et al. *Biochemistry*. 1997;36:5719–5728 (pg. 5719 abstract, pg. 5720 column 1 last paragraph, column 2, pg. 5727 column 1-2). Chen et al. Whiteheart SW. *Biochemical Biophysical Research Communications*. 1999;255: 340-346 (pg. 340 column 1-2, pg. 341 column 1-2 pg. 344 column 1-2).

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2. The technical feature of Group II is a method of making a medicament of the technical feature in Group 3, drawn to product comprising a SNARE and a kit and the technical feature of Group 4, drawn to nucleic acid encoding a SNARE, recombinant polynucleotide encoding a SNARE, gene therapy delivery system, and a kit.
3. The technical feature of Group III is a SNARE.
4. The technical feature of Group IV is a nucleic acid encoding a SNARE.

The technical feature of Group I, a method of treating a patient at risk by administering a SNARE to a cell. Group I lacks unity with Groups II-IV, because the technical feature of Group I is anticipated by the art and therefore not "special" within the meaning of PCT Rule 13.2 because it does not provide for a contribution that the claimed invention makes over the art.

Species Election

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. If the Applicant elects Group I or Group II, the Applicant is required to elect a single combination of individual species from each of Species A-C.

Group I & II are as follows:

Species A of SNARE

- 1) Synaptosomal-associated polypeptide of 25 kDA (SNAP-25)
- 2) Syntaxin 1
- 3) Synaptobrevin

Species B of inhibition

- 1) Polypeptide
- 2) Polynucleotide

Species C of cell type

- 1) Nerve cell
- 2) Insulin-secreting cell.

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If the Applicant elects Group III or Group VI, the Applicant is required to elect a single individual species from the species listed below.

Group III & IV Species as follows:

- 1) Variants of fragments that are least 18 amino acids in length
- 2) Variants of full length SNAP-25
- 3) Cysteine substitution at N-terminal position

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103 (a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina A. Archie whose telephone number is 571-272-9938. The examiner can normally be reached on Monday-Friday 8:30-5:00p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Acting supervisor, Mark Navarro can be reached on 571-272-0861. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Nina Archle

Patent Examiner

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PATRICIA A. DUFFY
PRIMARY EXAMINER